

RESPONSE

Rejection Under 35 U.S.C. § 112

The Examiner has objected to the use of the expression “spin-culture in claim 36, line 3. Claim 36 has now been amended to recite “spinner culture” which finds basis on page 48 next to the last line. It is a revolving culture chamber.

The Examiner has objected to the use of the expression “progenitor mesenchymal cells,” in claim 61, line 3. The Examiner is of the opinion that these cells while listed in the claims are not cells described as being useful in the invention. Applicants believe that when page 13 of this application is read together with the chart on page 14, the Examiner will find that “progenitor mesenchymal cells” are indeed part of this invention. This fact is further corroborated by the fact that claim 61 is an original claim, and the Markush group therein is to be read as part of the original disclosure.

Rejection 35 U.S.C. § 112

Claims 36-46 and 58-70 are rejected as not complying with the enablement requirement of 35 U.S.C. § 112. The Examiner states that “advantages” are only shown for chondrocytes and accordingly the claims should be limited only to chondrocytes. Applicants respond by pointing out that in order for a claim to be patentable a claim need not embrace any “advantage.” To be patentable the statute requires that the subject matter be “unobvious.” There is no statutory requirement for advantageousness. It is requested that in view of the above remarks, the rejection be withdrawn.

The Examiner has objected to the expression “collagen-coated biopolymers” in claims 43 and 67 as being unsupported by the disclosure. Applicants by amendment have canceled the expression “collagen-coated biopolymers”.

The claims have been amended to recite “spinner culture” which finds basis in the disclosure on page 48.

As previously pointed out, the statute, 35 U.S.C. § 103 does not require that the invention be “advantageous”. The statute requires that the subject matter be “unobvious”.

Claims 36 and 58 have been amended to avoid ambiguity caused by the expression “different part of the patient’s body”.

Claim 36 has been objected to in the use of the term “high quality”. In claim 36 is defined as being chondrocytes which regenerate in the body to produce a “long-term cure”.

Claim 36 is objected to in the use of “spin-culture”. This expression has been changed to “spinner culture”. A term supported by the disclosure.

In claims 38 and 62, “orthopedic purposes” refers to its conventional use as repairing “limb-structure”. Certainly the expression “orthopedic surgeon” is well known.

The term “conveniently” has been removed from claims 37, 59 and 60.

Claims 43 and 67 are now amended to be consistent as to terminology.

Regarding the expression “reduced oxygen environment” in claims 40 and 64, attention is directed to pages 45-47 of the specification which are clearly exemplary of the expression.

Regarding the application naming joint inventors and the potential for a rejection under 35 USC § 102 or 35 USC § 103. Applicants state that joint inventors made assignments to Chondros, Inc. and other joint inventors made assignments to Johns Hopkins University. Chondros, Inc. has an undivided interest and Johns Hopkins University has granted an exclusive license to Chondros, Inc. It is noted that thus far the ownership issue is moot since no rejection under 35 USC § 102 or 35 USC § 103 has been made involving this issue.

Rejection 35 USC § 103

Claims 36-39, 42-46, 58-63 and 66-70 stand rejected under 35 USC § 103 over *Glorioso et al* in view of *Frondoza et al* and *Schinistine et al, Cherksey* and is necessary further in view of *Armstrong*. For the reasons which follow, it is believed that these references cannot be properly combined to make a valid rejection under 35 USC § 103.

While it is true that *Frondoza et al* teach spin-culture of chondrocytes, *Frondoza et al* cannot be combined with *Glorioso et al* because *Glorioso et al* employ transfected cells and *Frondoza et al* employ unaltered chondrocytes. It is believed that transfection would alter the nature of the chondrocyte and combining *Glorioso et al* with *Frondoza et al* amounts to combining non-analogous art.

Regarding *Schinistine et al* the Examiner has failed to point out wherein *Schinistine et al* deal with chondrocytes and no reference made of record shows the equivalence between chondrocytes and the cells set forth by *Schinistine et al*. Further, note that *Schinistine et al* control the growth of cells within an implantable bioartificial organ and inhibits cell proliferation.

Applicants do not require such a bioartificial organ, but can implant without the use of a bioartificial organ.

Regarding *Cherksey*, it is believed that *Cherksey* who deals with methods for increasing the viability of cells which are to be administered to the brain or spinal cord cannot be combined with *Frondoza et al* who deal with chondrocytes used for cartilage repair. Clearly combining *Cherksey* and *Frondoza et al* amounts to improperly combining non-analogous art.

Regarding Armstrong, it is respectfully pointed out that Armstrong is concerned with living skin replacement and employs proliferative skin cells. On the other hand, applicants are concerned with chondrocytes for cartilage replacement. Clearly, Armstrong is for a concept distinct from applicants and cannot be properly combined with the remaining references to make a valid rejection under 35 USC § 103.

Applicants point out that there is no impediment to employing multiple references to reject a claim, however, in the instant application the Examiner has combined non-analogous art to make his rejection.

Claims 40, 41, 64 and 65 stand rejected under 35 USC § 103 on the grounds addressed above, further in view of *Starling*. A review of *Starling* indicates that "cultures were maintained in a carbon dioxide incubator". However, there is no suggestion that *Starling* contemplates "spinner culture" as required by the claims. Instead *Starling* uses "Petri dishes". Further, the Examiner has not shown the percentages of oxygen as required by claims 41 and 65.

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It is further pointed out that in making his rejections the Examiner has failed to show a reference employing "nasal septal cartilage" as in claim 37; the percent of oxygen as in claims 41 and 65; the specific compounds of claims 44, 46, 59 and 68-70. These are important features and should be addressed by the Examiner.

All objections and rejections have been addressed. It is requested that the Examiner find allowable subject matter in this application.

Sincerely,

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Date

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SR/jjr (01/26/05)

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